

Application No: 10/002,521
Amendment and Response dated March 2, 2006
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REMARKS

Applicants would like to thank Examiner Patterson for the personal interview with Applicants' representatives on February 22, 2006. The subject matter discussed was Applicants' amended claims as set forth herein in view of the cited art.

Claims 1-3, 21, 22 and 24-26 remain in this application. Claims 1, 3, 22, 25 and 26 have been amended. Applicants respectfully request reconsideration in view of the above amendments and the following remarks.

Applicants' Response to 35 U.S.C. §102 Rejection over Yen

Claim 26 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 4,906,377 to Yen et al. (hereinafter "Yen") as evidenced by U.S. Patent No. 5,776,185 to Verona et al. Applicants respectfully request reconsideration on the basis that Yen fails to disclose each and every element of Applicants' amended claim 26.

The Examiner contends that Yen discloses PTFE, which is extruded, having a liquid polymeric component that is incompatible with the PTFE. More specifically, according to the Examiner, Yen discloses an oligomer, which is a liquid and which is phase separated, therefore comprising discrete domains that are incompatible. The Examiner further asserts that the oligomer may be extracted to create pores in the resin. The Examiner admits that Yen does not disclose an extrudate that permits tissue growth upon implantation. The Examiner, however, points to Verona's disclosure that PTFE is biocompatible. According to the Examiner, the property of permitting tissue growth is therefore inherent to Yen.

Applicants have amended claim 26 herein to further define the PTFE extrudate. In particular, Applicants have amended claim 26 to recite that the extrudate is "extruded in the form of a tube." This amendment is supported by disclosure at page 16, paragraph 61 of the specification, as filed.

Yen discloses extrusion of a melt blend of poly(tetrafluoroethylene-co-perfluoro(alkyl vinyl ether)) (PFA) or poly(tetrafluoroethylene-co-hexafluoropropylene) (FEP) and an oligomer solvent in the form of a sheet membrane. Yen states that the extruded sheet membrane, or film, may be rolled onto a core for storage. Extrusion in the form of a sheet membrane and subsequent rolling or wrapping to form the shape of a tube for storage is distinctly different from extrusion in the form of a tube. Nowhere in Yen is extrusion in the form of a tube disclosed or suggested. Because Applicants' amended claim 26 requires extrusion in the form of a tube, Yen fails to disclose each and every element of the claim. As such, Yen cannot anticipate Applicants' amended claim 26.

Furthermore, Yen merely discloses extrusion of PFA or FEP, both of which are co-polymers. Neither of these materials is PTFE, which is not a co-polymer. Nowhere in Yen is extrusion of PTFE disclosed or suggested. Accordingly, Yen fails to disclose a PTFE extrudate.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the Section 102 rejection over Yen.

Applicants' Response to 35 U.S.C. §103 Rejection over Cabasso in view of Yen

Claims 1 and 21 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent No. 4,951,381 to Cabasso in view of Yen. The applicant of U.S. Patent No. 4,951,381 is not Cabasso and the field of art is not relevant to the present application. In the interest of furthering the prosecution of the present application, Applicants conducted a search in an attempt to determine the proper Cabasso reference. Applicants uncovered U.S. Patent No. 4,954,381 to Cabasso (hereinafter "Cabasso"), which Applicants confirmed at the interview to be the correct Cabasso reference for purposes of this response. Applicants respectfully request reconsideration on the basis that the combination of Cabasso and Yen fails to teach or suggest Applicants' claims 1 and 21, as amended herein, and hence fails to make out a *prima facie* case of obviousness.

The Examiner contends that Cabasso discloses a medical device that is implantable and comprises a PTFE matrix having a polymeric material therein that is extractable upon exposure to dissolving medium to create pores in the matrix. According to the Examiner, the extractable material of Cabasso is enveloped by a crosslinked polymer shell, and thus, comprises an interpenetrating polymer network.

The Examiner acknowledges that Cabasso does not disclose a tubular extrudate. In particular, the Examiner admits that Cabasso merely discloses a membrane made by solvent casting. The Examiner points to Yen for extrusion and formation of a tube. As discussed above, however, Yen merely discloses rolling an extruded sheet membrane onto a core for storage. A tube formed by rolling an extruded sheet is distinctly different from extrusion in the form of a tube. As in claim 26, discussed above, Applicants have amended claims 1 and 21 herein to recite that the tubular extrudate is “extruded in the form of a tube.” Nowhere in Yen or Cabasso is extrusion in the form of a tube disclosed or suggested. Moreover, there is no suggestion in Cabasso or Yen to modify the teachings to extrude the materials in the form of a tube.

Furthermore, Applicants also have amended claims 1 and 21 herein to further define the form of the extractable polymeric material. In particular, amended claims 1 and 21 require a solid extractable polymer material. This amendment is supported by disclosure at page 9, paragraph 35 of the specification, as filed. Neither Cabasso nor Yen discloses an extractable polymeric material in a solid form. Both Cabasso and Yen extract fluids (solvents) as opposed to solid polymeric material. There is no suggestion in either reference to modify the teachings to extract a solid as opposed to the fluids. As such, the cited combination also fails to teach or suggest Applicants’ amended claims on this ground.

For the reasons expressed above, Applicants respectfully request reconsideration and withdrawal of the Section 103 rejection over Cabasso in combination with Yen.

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Applicants' Response to 35 U.S.C. §103 Rejection over Cabasso in view of Yen and Chuter

Claims 2, 3, 22, 24 and 25 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Cabasso in view of Yen and U.S. Patent No. 6,293,969 to Chuter (hereinafter "Chuter"). As in the Section 103 rejected discussed above, Applicants assume U.S. Patent No. 4,954,381 to be the correct Cabasso reference for purposes of this response. Applicants respectfully request reconsideration on the basis that the cited combination fails to teach or suggest Applicants' claims, and hence fails to make out a *prima facie* case of obviousness.

With respect to claim 2, the Examiner acknowledges that Cabasso and Yen fail to disclose a radially distensible stent positioned axially about the tubular extrudate. The Examiner, however, cites Chuter for its disclosure of stents. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to provide for the stent of Chuter in Cabasso and Yen.

Because claim 2 depends from independent claim 1, it contains all of the recitations of claim 1, as amended herein. As discussed above, Cabasso and Yen fail to disclose, teach or suggest a tubular extrudate that is extruded in the form of a tube, as well as an extractable polymeric material that is solid. Because Chuter was cited merely for its disclosure related to stents, it fails to cure the deficiencies of Cabasso and Yen in this regard. In view thereof, claim 2 is not obvious in view of the teachings of Cabasso in combination with Yen and Chuter.

With respect to claim 3, the Examiner contends that the stent disclosed by Chuter is a vascular graft. As in claims 1 and 21, discussed above, Applicants have amended claim 3 to recite that the tubular extrudate is "extruded in the form of a tube" and to require the extractable polymeric material to be solid. As discussed above, neither of these recitations is disclosed or suggested in Yen or Cabasso, and Chuter fails to cure the deficiencies of Cabasso and Yen in this regard. Accordingly, claim 3 also is not obvious in view of the teachings of Cabasso in combination with Yen and Chuter.

As regards claim 22, the Examiner asserts that the extractable material disclosed by Cabasso is particulate because Cabasso discloses droplets. The droplets disclosed in Cabasso are spherical liquid droplets. Applicants have amended claim 22 herein to require the extractable polymeric material to be solid. As discussed above, Cabasso and Yen fail to disclose or suggest a solid extractable material. Applicants also have amended claim 22, as in claims 1, 3 and 21, to require the tubular extrudate to be “extruded in the form of a tube.” As above, Chuter fails to cure the deficiencies of Cabasso and Yen in this regard. Therefore, claim 22 also is not obvious in view of the teachings of Cabasso in combination with Yen and Chuter.

With respect to claim 24, the Examiner asserts that Cabasso and Yen do not disclose a component other than PTFE and an extractable polymeric material. According to the Examiner’s reasoning, Cabasso and Yen therefore disclose a device “consisting essentially of” PTFE and a polymeric component.

First, as discussed above, Yen does not disclose PTFE, but rather discloses extrusion of a co-polymer, i.e., PFA or FEP, and an oligomer solvent. PFA and FEP are both co-polymers, which are formed by the reaction of two polymers to obtain a new copolymer molecule. These copolymers are entirely different compounds than PTFE. Yen therefore discloses a component other than PTFE. As such, Yen cannot “consist essentially of” PTFE and an extractable polymeric material.

Second, claim 24 is directed to an intermediate product in which the extractable polymeric material is distributed throughout the PTFE resin, but has not yet been extracted therefrom. The claimed intermediate “consists essentially of” PTFE and the extractable polymeric material. In contrast, the intermediate product of Cabasso includes solvents in addition to its polymers A and B. More specifically, Cabasso discloses a dispersion of a water-soluble polymer solution A in an organic polymer solution B. Both polymer A and polymer B are in solution, and thus, must include solvents. Because Cabasso’s intermediate product includes solvents, it cannot “consist essentially of” polymer A and polymer B. As such,

Cabasso's intermediate cannot "consist essentially of" PTFE and an extractable polymeric material.

Moreover, Cabasso's end-product is equally inapplicable against Applicants' claim 24. In Cabasso's end-product, polymer A and polymer B have reacted, complexed or polymerized with one another at their interface. For example, Cabasso's end-product may include a copolymer of polymers A and B. The reaction to form a copolymer forms a new polymer molecule, not separate and distinct polymer components. (Cabasso; Col. 4, lines 23-46). In contrast, Applicants' claim 24 requires discrete domains of an extractable polymeric component, i.e., a separate and distinct polymer component. The discrete domains are naturally formed as a result of admixing PTFE with an extractable polymeric material that is sufficiently incompatible with the PTFE to physically separate therefrom and form its own region or domain with the PTFE. (Applicants' specification; page 8, ¶34; page 9, ¶38; page 15, ¶56; Fig. 7). Such discrete domains of an extractable polymeric material are distinctly different from chemically copolymerized polymers. As such, Cabasso's end-product also fails to teach or suggest Applicants' claim 24.

Moreover, there is no suggestion in Cabasso or Yen to modify their teachings to "consist essentially of" PTFE and discrete domains of an extractable polymeric component. In view thereof, Cabasso and Yen, each taken alone or in combination, fail to disclose or suggest a device "consisting essentially of" PTFE and discrete domains of an extractable polymeric component, as recited in Applicants' claim 24. Although the Examiner does not specifically refer to any portions of Chuter in the rejection of claim 24, Chuter was cited merely for its disclosure related to stents and fails to cure the deficiencies of Cabasso and Yen in this regard. Therefore, claim 24 also is not obvious in view of the teachings of Cabasso in combination with Yen and Chuter.

With respect to claim 25, the Examiner asserts that "the extractable polymeric material disclosed by Cabasso [] and Yen [] comprises polyvinyl alcohol." (Office Action dated

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December 2, 2005, at 5). Applicants have amended claim 25 herein to remove polyvinyl alcohol. In view thereof, Applicants respectfully submit that this Section 103 rejection has been overcome.

In view of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the Section 103 rejections over Cabasso in combination with Yen and Chuter.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

Respectfully submitted,



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